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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/643,554

08/22/2000

Richard Alan Fiedotin

61018-0008-US

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06/14/2006

MORGAN, LEWIS & BOCKIUS, LLP.

2 PALO ALTO SQUARE

3000 EL CAMINO REAL

PALO ALTO, CA 94306

EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/643,554

Applicant(s)

FIEDOTIN ET AL.

Examiner

Luke Gilligan

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. In the response filed 3/21/06, the following has occurred: no claims have been added, amended, nor canceled. Now, claims 1 and 3-35 are presented for examination.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-7, 11, 15, 16, 18, 20, 21, and 26-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Halvorson, U.S. Patent No. 4,847,764.
4. As per claim 1, Halvorson teaches a method for renewing a prescription for a pharmaceutical via an electronic network, comprising the steps of: computing monitoring an expiration date of a prescription by periodically determining whether a predetermined time period before said expiration date has been reached (see column 5, lines 27-29); computing generating a prescription renewal request for the renewal of said prescription prior to said expiration date based on said computer monitoring, wherein said generating occurs without human intervention (see column 5, lines 29-32 the Examiner considers informing each physician of orders that require renewal to be generation of a prescription renewal request); transmitting said prescription renewal request to a prescriber (see column 5, lines 29-32); receiving a renewal prescription, in response to said prescription renewal request, from said prescriber (see column 4, lines 28-32 and column 10, line 40, note that all prescriptions must be authorized by a physician); and notifying a dispenser to fill said renewal prescription (see column 4, lines 28-32).

Art Unit: 3626

5. As per claim 3, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches creating said prescription renewal request from the following: a patient identifier, a pharmaceutical identifier, a dispenser identifier, a prescription identifier, a prescriber identifier, a dosage, number of refills, and a strength (see column 10, lines 1-43).

6. As per claim 4, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches prior to said receiving step, providing information useful to said prescriber for reviewing said prescription renewal request (see column 4, lines 43-55).

7. As per claim 5, Halvorson teaches the method of claim 4 as described above.

Halvorson further teaches said information is selected from the following: warnings for any drug-drug reactions, formulary listings, patient medication history, and low cost therapeutic alternatives (see column 4, lines 43-55).

8. As per claim 6, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches said receiving step further comprises the step of acquiring a renewal prescription, wherein said renewal prescription has components that have been changed from said prior prescription (see column 16, lines 51-63).

9. As per claim 7, Halvorson teaches the method of claim 6 as described above.

Halvorson further teaches said components are selected from the following a patient identifier, a pharmaceutical identifier, a dispenser identifier, a prescription identifier, a prescriber identifier, a dosage, number of refills, and a strength (see column 10, lines 1-43).

10. As per claim 11, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches the steps of claim 1 occur for a plurality of prescription renewal requests and renewal prescriptions (see column 14, lines 55-65).

Art Unit: 3626

11. As per claim 15, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches deleting said prescription renewal request after a set time (see column 15, lines 16-28).

12. As per claim 16, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches deleting said renewal prescription after a set time (see column 15, lines 16-28).

13. As per claim 18, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches determining whether a prescribed pharmaceutical from said prior prescription is on formulary (see column 8, line 24); and dispensing said prescribed pharmaceutical based on said determining step (see column 8, line 25).

14. As per claim 20, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches the initial step of determining whether refills are available for said prior prescription (see column 23, lines 26-31).

15. As per claim 21, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches obtaining a patient record, said obtaining a patient record, said record containing at least a patient identifier, a pharmaceutical identifier for a currently prescribed pharmaceutical, a number of authorized refills of the currently prescribed pharmaceutical, and a date of the last filling of the currently prescribed pharmaceutical (see column 10, lines 1-30); and setting a renewal date before a last refill has been consumed by a patient if said number of authorized refills is greater or equal to a predetermined number (see column 14, lines 58-65).

16. As per claim 26, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches determining when a prescribed refill will expire (see column 5, lines 27-32); setting a renewal date prior to expiration of said prescribed refill (see column 14, line

Art Unit: 3626

44); and periodically determining whether said renewal date has been reached (see column 5, lines 27-32).

17. As per claim 27, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches said prescription comprises multiple prescriptions for a patient (see column 4, lines 47-52).

18. As per claim 28, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches said prescription comprises multiple prescriptions for multiple patients (see column 4, lines 47-52).

19. As per claim 29, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches said prescription comprises a prescription for multiple patients (see column 4, lines 56-59).

20. As per claim 30, Halvorson teaches the method of claim 1 as described above.

Halvorson further teaches said computer monitoring occurs without patient intervention (see column 5, lines 27-32).

21. Claims 31-35 recite substantially similar limitations to those already addressed in claims 1 and 3-6 with the exception that the claims do not require any computer involvement, nor are there any limitations specifying who or what generates a prescription renewal request.

Therefore, since claims 31-35 are merely broader versions of claims 1 and 3-6, they are rejected for similar reasons as given above.

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3626

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claims 8-10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halvorson, U.S. Patent No. 4,847,764 in view of Mayaud, U.S. Patent No. 5,845,255.

24. As per claim 8, Halvorson teaches the method of claim 1 as described above. Halvorson does not explicitly teach acquiring an appeal from a patient to contact said prescriber. Mayaud teaches acquiring an appeal from said prescriber for a patient of said prior prescription to contact said prescriber (see column 23, lines 29-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the system of Halvorson. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of communicating emergency information to a patient to enhance the safety of the patient (see column 23, lines 30-32).

25. As per claim 9, Halvorson in view of Mayaud teach the method of claim 8 as described above. Halvorson does not explicitly teach notifying said dispenser to inform said patient to contact said prescriber. Mayaud further teaches said acquiring step further comprises notifying said dispenser to inform said patient to contact said prescriber (column 23, lines 29-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the system of Halvorson for the reasons given above with respect to claim 8.

26. As per claim 10, Halvorson in view of Mayaud teach the method of claim 8 as described above. Halvorson does not explicitly teach notifying said patient to contact said prescriber. Mayaud further teaches said acquiring step further comprises notifying said patient to contact said prescriber (see column 23, lines 29-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the system of Halvorson for the reasons given above with respect to claim 8.

Art Unit: 3626

27. As per claim 19, Halvorson teaches the method of claim 18 as described above.

Halvorson does not explicitly teach ascertaining whether said prescribed pharmaceutical is a chronic medication and storing the result. Mayaud teaches ascertaining whether said prescribed pharmaceutical is a chronic medication (see column 20, lines 41-49 and Figure 3, the patient history would indicate if a prescription had been prescribed for a chronic illness); and storing a result of said ascertaining step (see column 20, lines 41-49 and Figure 3, this result is at least temporarily stored in the memory of the portable computing device). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Mayaud. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of enhancing the automatic inventory control aspect of Halvorson by accounting for medications that will need to be utilized on a recurring basis for chronically ill patients (see 5, lines 43-50 of Halvorson).

28. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halvorson, U.S. Patent No. 4,847,764 in view of **nevoca.com Enhances Prescription Verification System** (hereinafter nevoca).

29. As per claim 12, Halvorson teaches the method of claim 1 as described above. Halvorson does not explicitly teach ascertaining a status of said prescription renewal request. Nevoca teaches ascertaining a status of said prescription renewal request (see paragraph 9). It would have been obvious to one of ordinary skill in the art of prescription management at the time of the invention to include this feature in the system of Halvorson. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of decreasing time spent processing prescriptions (see paragraph 2 of nevoca).

Art Unit: 3626

30. As per claim 13, Halvorson in view of nevoca teach the method of claim 12 as described above. Halvorson does not explicitly teach determining how many prescription renewal requests were transmitted to said prescriber and establishing how many prescription renewal requests said prescriber has addressed. Nevoca teaches these determining and establishing steps (see paragraph 9, the Examiner asserts that these steps would be necessary to determining the "exact status" when a doctor has not yet responded to a prescription renewal request). It would have been obvious to one of ordinary skill in the art of prescription management at the time of the invention to include this feature in the system of Halvorson for the reasons given above with respect to claim 12.

31. As per claim 14, Halvorson in view of nevoca teach the method of claim 12 as described above. Halvorson does not explicitly teach sending the status to said prescriber. Nevoca teaches said ascertaining step further comprises the step of sending said status to said prescriber (see paragraphs 4 and 9). It would have been obvious to one of ordinary skill in the art of prescription management at the time of the invention to incorporate this feature into the system of Halvorson for the reasons given above with respect to claim 12.

32. Claims 17 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halvorson, U.S. Patent No. 4,847,764 in view of **Biomerica and Viking Components Announce Strategic Partnership for Final Phase of ReadyScript** (hereinafter ReadyScript).

33. As per claim 17, Halvorson teaches the method of claim 1 as described above. Halvorson further teaches accepting said prescription renewal request (see column 5, lines 27-32); displaying said prescription renewal request to said prescriber (see column 5, lines 27-32); showing said prescriber information useful for reviewing said prescription renewal request (see column 4, lines 47-55); and communicating said renewal request (see column 4, lines 28-33).

Art Unit: 3626

Halvorson does not explicitly teach a server and a portable computing device for communicating the various steps. ReadyScript discloses communicating prescription information from a web server to a portable computing device that is used by a prescriber (see paragraph 2), where such communication is used to automate the prescription renewal process between prescribers and dispensers (see paragraph 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a system architecture into the system of Halvorson. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of enhancing the convenience for patients of not having to wait for prescriptions to be filled by providing additional automation and technology in implementing the prescription renewal process of Halvorson (see paragraph 9).

34. Claims 22 and 23 contain substantially similar limitations to claims 1, 5 and 17 and, as such, are rejected for similar reasons as given above.

35. Claims 24 and 25 contain substantially similar limitations to claims 1 and 17 and, as such, are rejected for similar reasons as given above.

Response to Arguments

36. In the remarks filed 3/21/06, Applicants argue in substance that (1) the "order" of Halvorson is not a form of "prescription" as recited in the claims; (2) renewing "orders" in Halvorson is not a form of renewing a "prescription" as recited in the claims; (3) the Medication Discontinue Notice report of Halvorson is not a form of "prescription renewal request" as recited in the claims; (4) Halvorson does not teach that the transmitting and receiving steps are performed via an electronic network as recited in the preamble; (5) Halvorson does not teach a renewal prescription in response to a prescription renewal request.

Art Unit: 3626

37. In response to Applicants' argument (1), it is respectfully submitted that a renewed order, as described in Halvorson, is identical to Applicants' own definition of a "renewal prescription" as described at page 3 of the specification and pointed out at page 8 of the Remarks. Applicants' definition includes two conditions: first, it is based at least in part upon the original prescription; second, it requires a new authorization from the physician. Clearly, a renewed order in Halvorson is based at least in part upon an original order since the entire purpose of notifying a physician of an order which needs to be renewed is to notify them of "drugs which a patient may need but are about to be discontinued" (see column 15, lines 12-13). In addition, as noted in the above rejections, Halvorson requires that all orders be authorized. This includes both new orders as well as renewal orders. The Examiner also wishes to direct Applicants' attention to the information that is included in each patient order (see column 10, lines 1-43). In particular, note that items 9 and 30 indicate both the "date and time of last renewal" and the "identification of the ordering physician." This combination of data is clearly identical to the claimed "renewal prescription" with the only difference being that of mere labeling. Therefore, the Examiner respectfully maintains that the "order" of Halvorson is a type of "prescription" as claimed.

38. With respect to Applicants' assertion that claim 22 in Halvorson distinguishes prescriptions from orders, it is unclear to the Examiner how the phrase "in accordance with" draws any kind of particular distinction between the two terms. Given that there is no other mention of the term "prescription" in the specification of Halvorson, and given that the combination of data that makes up a "patient order" appears to be identical to that of a "prescription," it is respectfully submitted that the mere mention of this phrase in the claim of Halvorson does not distinguish the term "order" from the term "prescription" as claimed by Applicants.

Art Unit: 3626

39. In response to Applicants' argument (2), as noted above in response to argument (1), it is respectfully submitted that the "order" of Halvorson is a type of "prescription" as claimed. As also, described above in response to argument (1), the "renewal order" of Halvorson meets the conditions of Applicants' definition of a "renewal prescription" (i.e. based in part on original order and authorized by a physician). Therefore, it is respectfully submitted that a renewed order is a type of renewal prescription as claimed.

40. In response to Applicants' argument (3), since the purpose of the report that is presented to the physician is to "notify physicians of any drugs which a patient may need but are about to be discontinued" (see column 15, lines 12-13), it is unclear how this could be construed in any other way than as a request to renew the orders for those drugs that a patient may need. It is respectfully submitted that this statement of purpose from Halvorson, along with the fact that every order, both original and renewal, requires physician authorization, clearly constitutes a "renewal request" as claimed.

41. In response to Applicants' argument (4), it is respectfully submitted that the preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In the case of claims 1 and 31, the steps recited in the body of the claims make no reference to the electronic network recited in the preamble. Therefore, the Examiner does not find this argument to be persuasive since the steps are not explicitly recited as being performed via an electronic network.

42. In response to Applicants' argument (5), as established above, the Examiner is interpreting the Medication Discontinue Notice report, which is presented to the physician, to be

Art Unit: 3626

a type of renewal request. In addition, as noted above, every order, both original and renewal, requires authorization from the ordering physician. Therefore, it is respectfully submitted that a renewal patient order, such as the one shown at column 10, lines 1-43, is "in response to" a renewal request since the report notifies the physician of every order that is about to be discontinued unless renewed(see column 14, line 55 – column 15, line 13).

Conclusion

43. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

44. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

45. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (571) 272-6770. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

46. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3626

47. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

6/9/06



C. LUKE GILLIGAN
PATENT EXAMINER